IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| ABBOTT DIABETES CARE, INC., | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | C.A. No. 05-590 (GMS) |
| | ) | |
| DEXCOM, INC., | ) | **REDACTED** |
| | ) | **PUBLIC VERSION** |
| Defendant. | ) | |
| | ) | |

**ABBOTT'S ANSWERING BRIEF IN OPPOSITION TO DEXCOM'S MOTION TO STRIKE "AMENDED COMPLAINT" AND RENEWED MOTION TO DISMISS**

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TABLE OF CONTENTS

TABLE OF CITATIONS

Cases

Statutes



Other Authorities



Rules

## NATURE AND STAGE OF PROCEEDINGS AND SUMMARY OF ARGUMENT

In an effort to avoid an inevitable infringement finding, DexCom is wasting the Court's time with its latest motion papers, which consist of a motion to strike Abbott's amended complaint and a renewed motion to dismiss for lack of subject matter jurisdiction. DexCom ignores the obvious reality that Abbott could have filed a new complaint in this jurisdiction at any time, that the new case would likely have been consolidated with the current case before this Court, and that DexCom would have had no grounds to challenge the filing. In other words, even if it were well founded (and it is not), DexCom's current motion can accomplish nothing. It will never have a practical effect. Thus, it is not at all clear why DexCom is taking issue with Abbott's efficient choice to file an amended complaint – a filing made before the deadline for filing amended pleadings specifically set forth in the scheduling order, which, by itself, should resolve the issue.

DexCom's purported motion to strike Abbott's Amended Complaint is based on a hypertechnical argument related to Fed R. Civ. P. 15 that has no merit. Specifically, DexCom tries to raise a distinction between an amended and a supplemental complaint that is both legally and factually flawed. Abbott filed its Amended Complaint as of right under Rule 15(a) because DexCom had not yet answered. It did so within the time allotted by the Court for amending the pleadings. At the time Abbott filed its initial complaint, DexCom had already infringed Abbott's patents; the fact that DexCom engaged in further infringing activities does not render Abbott's pleading a "supplemental complaint" requiring leave of the Court. In the end, however, regardless of how this complaint is classified by the Court, leave to amend in these situations should

be "freely granted." If the Court finds that leave is required, Abbott affirmatively requests it.

In the alternative, DexCom seeks dismissal on the purported ground that subject matter jurisdiction was lacking at the time Abbott filed its initial Complaint, because DexCom's product had not yet received FDA approval. Unfortunately for DexCom, its own papers demonstrate that jurisdiction was proper when Abbott filed its initial Complaint. Declaratory jurisdiction as well as jurisdiction under the patent laws existed because DexCom was preparing to launch its product, DexCom engaged in actual infringement by showcasing its product at trade shows, and, when Abbott informed DexCom of its patents, DexCom continued to showcase its product at these trade shows.

DexCom's jurisdiction argument is nothing more than a rehash of the arguments it made in its first motion to dismiss and is based on a faulty premise: that FDA approval must be granted before a patentee can sue under the Declaratory Judgment Act or for patent infringement. This is not the law. Instead, the law is that declaratory jurisdiction exists if the dispute between the parties is both real and immediate, regardless of FDA approval status. As Abbott demonstrated in its earlier briefs, several courts have found declaratory jurisdiction to exist *before* the FDA has given approval in situations where the infringer was engaged in the process of seeking FDA approval. In this case, when Abbott filed its initial Complaint, FDA approval of DexCom's product was imminent. In DexCom's initial motion to dismiss, DexCom argued disingenuously that FDA approval for its product was "speculative." As Abbott demonstrated, however, DexCom had completed enough milestones to make its approval a forgone conclusion. In fact, DexCom received FDA approval *even sooner* than Abbott alleged in its initial

Complaint – in the first quarter of 2006. In the end, Abbott was correct; DexCom was about to get approval. DexCom's assertions that jurisdiction was lacking are belied by the fact that it is presently on the market and currently selling infringing devices. At the time Abbott filed its initial Complaint, the dispute between the parties was both real and immediate. Moreover, at the time Abbott filed its initial Complaint, this Court had subject matter jurisdiction under the patent laws, because DexCom was already infringing Abbott's patents through its activities at the trade shows.

## STATEMENT OF FACTS

On August 11, 2005, Abbott filed a two count Complaint alleging patent infringement and seeking declaratory relief stemming from four patents. (D.I. 1). Specifically, Abbott alleged that DexCom had infringed Abbott's patents and would continue to infringe Abbott's patents when it received FDA approval of its STS continuous glucose monitoring system, then expected in the second quarter of 2006. (*Id.* at ¶¶ 22, 24).

In an effort to avoid dealing with this matter on the merits, DexCom has engaged in a variety of delay tactics, including denying that the launch of its product was imminent and avoiding its discovery obligations. DexCom's pattern of delay was first highlighted to this Court at a scheduling conference in February 2006, prior to which DexCom refused to discuss a discovery schedule with Abbott, claiming that discussion of a schedule was unnecessary until the Court ruled on jurisdiction. (Tr. of Feb. 23, 2006 Hearing at pp. 2:19-3:18; attached hereto as Ex. A). Abbott was requesting this discovery, among other reasons, to do further review of DexCom's infringing product, as well as to respond to DexCom's contentions that the Court lacked jurisdiction to hear the case because FDA approval of DexCom's product was highly speculative. The Court

agreed that discovery should proceed, specifically including a Rule 30(b)(6) deposition on the status of the FDA review process. (*Id.* at p. 29:10-14).

Despite the Court's directive at the scheduling conference, DexCom continued to delay in fulfilling its discovery obligations. With respect to document production, DexCom failed to make a meaningful document production until June 2006, and it has yet to answer Abbott's contention interrogatories. In addition, instead of complying with the Court's order to produce a Rule 30(b)(6) witness, DexCom produced an unprepared witness who could not answer even basic questions related to the status of FDA approval.

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(L. Johnson Dep. at pp. 34:25-35:2; attached hereto as Ex. B).

Shortly after this deposition, DexCom received FDA approval for its product, obviating the need for Abbott to seek Court intervention related to the unprepared witness. However, despite that approval, DexCom did not produce a product sample and other documents that would have enabled Abbott to conduct further analysis of DexCom's product until June 2006. Abbott then amended its Complaint on June 27, 2006 -- before the July 14, 2006 deadline for amending the pleadings. This was Abbott's first amendment, which it made pursuant to Rule 15(a) because DexCom had not filed a responsive pleading. The amendment added three additional Abbott patents, bringing the total number of patents asserted against DexCom to seven.

Throughout this whole process, DexCom continued to deny that its launch was imminent, even though it had passed virtually every milestone necessary to obtain FDA approval. For example, at the scheduling hearing on February 23, 2006, DexCom represented that its "FDA situation is *essentially identical* to what it was when this case was filed on August 11, [2005]" that "*no material step* has occurred within the FDA at this point," that DexCom was "*right in the middle* of the FDA process," and that there "remains a *material likelihood* that [DexCom] will be asked to modify [its] product." (Ex. A at p. 10:6-8 (emphasis added)). Critically, DexCom also assured the Court that there would be a 30-day notice period before a product launch:

> Again, the approvable letter will lead to at least the 30-day period that counsel is asking for. That will be disclosed.
>
> THE COURT: So there's at least 30 days between the issuance of the approvable letter and the ---
>
> MR. DOYLE: Exactly, Your Honor. That is the best case, if everything goes well and we get a lot of attention from the FDA. And the FDA is a busy place, so we can't really count on that.

(*Id.* at pp. 27:15-28:8; emphasis added).

At the hearing, DexCom also stated that there was a "significant likelihood" that the FDA would require an extra step of regulatory review called "panel review" that could substantially delay DexCom's approval:

> *If it goes to panel review, then we would be lucky to have a product anytime in 2006.* Thus, again, the reason – and I apologize, Your Honor, I did not mean any offense to the Court – it just seemed impossible to me, given still, the *significant likelihood that we will go to a panel review*, that I could honestly state to your Court when we would be prepared to make disclosures and to agree to a schedule.

(Ex. A. at p. 26:18-20 (emphasis added)). During an earnings conference call that occurred four days later, however, DexCom's CEO stated that we "have *not* been notified about a need for us to go to panel for this device." (DexCom Earnings Call at p. 8 (emphasis added); attached hereto as Ex. C). As DexCom knew, it was about to receive approval, and it did on March 27, 2006. Despite this knowledge, DexCom continued to deny the launch was imminent up to its reply brief on its motion to stay, which was filed on March 21, 2006. The very next day, DexCom sent Abbott a letter saying the launch would occur within a week.

Despite the fact that DexCom has launched and is currently selling an infringing product – confirming all of Abbott's allegations in its initial Complaint – DexCom has renewed its motion to dismiss, in which it continues to assert that this Court lacks subject matter jurisdiction to hear Abbott's patent infringement claims. DexCom also seeks to strike Abbott's Amended Complaint on the ground that it should have been filed as a "supplemental complaint" because it includes allegations of DexCom's continued infringement. As set forth below, both of these arguments lack merit.

## ARGUMENT

### I. Abbott Properly Filed An Amended Complaint Under Rule 15(a).

DexCom's contention that the Court should strike Abbott's Amended Complaint on the ground that it should be considered a supplemental complaint is misplaced. If DexCom's position were correct, a patentee could never amend under Rule 15(a) prior to the filing of an answer if the infringer engaged in further infringement after the filing of the initial complaint.

**A. DexCom's Infringement of the New Patents was Occurring When Abbott Filed Its Initial Complaint.**

DexCom's motion ignores that Abbott sued for actual patent infringement in its initial Complaint. Abbott properly amended its Complaint under Rule 15(a) – before DexCom answered – to allege additional acts of infringement that occurred prior to and after Abbott's initial Complaint. *See* Fed. R. Civ. P. 15(a). "An amended pleading *generally* is a modification to incorporate events that were unknown but occurred prior to the filing of the original pleading."[1] MOORE'S FEDERAL PRACTICE, Section 9.5 [1] (emphasis added). "By contrast, a supplemental pleading refers to additions to include transactions or occurrences that take place after the filing of the original pleading." *Id.* DexCom's papers ignore that the infringement alleged by Abbott occurred before the initial Complaint was filed. Abbott included additional allegations of DexCom's continued infringement to reflect accurately the state of affairs at the time Abbott filed its Amended Complaint. Abbott's Amendment is properly considered an amended complaint under Rule 15(a).

**B. Even if the Court Concludes Leave Is Required, It Should Be Freely Granted.**

Because Abbott amended pursuant to Rule 15(a), leave is not required. *See* Moore's Federal Practice, at § 15.10 ("Whether leave is required depends on the point in the proceedings of the litigation."). Rule 15(a) permits a party to amend "the party's pleading once as a matter of course at any time before a responsive pleading is served." Fed. R. Civ. P. 15(a). A motion to dismiss is not considered a responsive

[1] All of Abbott's patents issued before the filing of the initial Complaint, with the exception of the '366 patent. This patent is a continuation of the '752 and '509 patents, which were asserted in the original Complaint.

pleading. *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000) ("[I]n typical case in which defendant asserts defense of failure to state claim by motion rather than in answer, plaintiff may amend complaint once as matter of course without leave of court"). Abbott amended as of right under Rule 15(a) because DexCom had not answered the Complaint.

Even if leave were required, "[c]ourts should allow amendments liberally when justice requires and in the absence of an apparent or declared reason to deny leave." (MOORE'S FEDERAL PRACTICE at § 15.14). "Rule 15 further enhances the policy of allowing liberal amendments by allowing the relation back of amendments under certain circumstances in order to avoid the tolling of the statute of limitations." (*Id.).*

Even if the Court were to consider Abbott's complaint a "supplemental pleading," "[t]he same principles that support the liberal amendment of pleadings also apply to supplemental pleadings." *Id.* at §15.19. Under the Scheduling Order dated March 10, 2006, the deadline for amending pleadings was July 14, 2006. (March 10, 2006 Scheduling Order; attached hereto as Ex. D). Abbott filed its Amended Complaint on June 27, 2006. Because Abbott amended within the time allotted by the court, its amended complaint should be allowed. *See Keith v. Volpe,* 858 F.2d 467, 473, 476 (9th Cir. 1988) ("The rule is a tool of judicial economy and convenience. Its use is therefore favored."); *see also*, *Quarantino v. Tiffany & Co.*, 71 F.3d 58, 66 (2d Cir. 1995) ("Again, leave to file a supplemental pleading should be freely permitted when the supplemental facts connect it to the original pleading."); *New Amsterdam Casualty Co. v. Waller*, 323 F.2d 20, 28-29 (4th Cir. 1963) ("So useful are [supplemental pleadings] and of such service in the efficient administration of justice that they ought to be allowed as of course . . . ."); *Novak v. National Broadcasting Co.*, 724 F. Supp. 141, 145 (S.D.N.Y. 1989) ("[T]he same

standards apply to motions under both [subdivisions (a) and (d)] of Rule 15. . . . Thus, leave to supplement should be freely granted"). This is consistent with Rule 15(d)'s purpose -- "to promote as complete an adjudication of the dispute between the parties as is possible." *LaSilvia v. United Dairymen of Arizona*, 804 F.2d 1113, 1119 (9th Cir. 1986).

Accordingly, if the Court determines that leave was necessary, Abbott expressly requests leave. DexCom's contentions that it would be prejudiced because Abbott amended shortly before claim construction are moot, because the parties agreed to request an extension of certain dates in the scheduling order, including claim construction, and the Court granted this request.

## II. This Court had Declaratory Jurisdiction Over the Original Complaint and Continues to Have Jurisdiction over the Amended Complaint.

In renewing its motion to dismiss, DexCom ignores the reality that (1) Abbott filed a patent infringement action over which this Court clearly had jurisdiction, and (2) Abbott was correct that the launch of DexCom's product was imminent. In fact, the launch occurred even sooner than Abbott anticipated. For these reasons, DexCom's motion to dismiss should be denied.

The Federal Circuit has made it clear that "[a] patent holder may seek a declaratory judgment that a person will infringe a patent in the future provided that there is an actual controversy that is both real and immediate." *Glaxo Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570-71 (Fed. Cir. 1997); *Lang v. Pacific Marine & Supply Co., Ltd.*, 895 F.2d 761, 764 (Fed. Cir. 1990). An actual controversy exists in an action for future infringement if: (1) the defendant is "engaged in an activity directed toward making, selling, or using subject to an infringement charge under 35 U.S.C. § 271(a), or [is] making meaningful preparation for such activity;" and (2) acts of the defendant "indicate

a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming." *Lang*, 895 F.2d at 764; *accord Novopharm*, 110 F.3d at 1571 (noting that "systematically attempting to meet the applicable regulatory requirements" for FDA approval indicates an intent to enter market); *Kos Pharm., Inc. v. Barr Labs, Inc.*, 242 F. Supp. 2d 311, 318 (S.D.N.Y. 2003) (holding that filing FDA application and embarking "upon a protracted and costly process of obtaining regulatory approval" demonstrates meaningful preparation sufficient to establish an actual controversy); *Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1008 (N.D. Ill. 2001) (hereinafter "*Glaxo I*") (same). Abbott's initial Complaint met both parts of this test.

### A. DexCom's Argument That FDA Approval Is Required For Jurisdiction Ignores The Law and The Facts.

DexCom's briefs ignore the Federal Circuit's two-part test, and insist that the only fact that matters for determining jurisdiction is whether DexCom had obtained FDA approval. DexCom is simply wrong; if that were the case, jurisdiction would never exist before FDA approval.

Unfortunately for DexCom, FDA approval is not the standard that courts use to decide these issues. Declaratory judgment actions are "proper even though there are future contingencies that will determine whether a controversy ever becomes real." WRIGHT & MILLER, 10 Fed. Pract. & Proc. Civ. 3d § 2757. To determine whether to exercise jurisdiction in such circumstances, courts "focus on the practical likelihood that the contingencies will occur." *E.R. Squibb & Sons, Inc. v. Lloyd's & Cos.*, 241 F.3d 154, 177 (2d Cir. 2001) (quoting *Associated Indemnity Corp. v. Fairchild Indus., Inc.*, 961 F.2d 32 (2d Cir. 1992)); *Chevron U.S.A. Inc. v. Traillour Oil Co.*, 987 F.2d 1138, 1153

(5th Cir 1993) (same); *Seippel v. Jenkens & Gilchrist, P.C.*, 341 F. Supp. 2d 363, 383 (S.D.N.Y. 2004) (same); *Molitch v. Brotman*, No. Civ. A. 96-7742, 1997 WL 431008, at *2 (E.D. Pa. July 15, 1997) (noting that declaratory plaintiff need not establish that the prospect of injury "is a mathematical certainty" and, instead, jurisdiction is appropriate if the threat of future injury is "real and substantial."); WRIGHT & MILLER, 10 Fed. Prac. & Proc. Civ. 3d §2757 (courts should look to the "practical likelihood that the contingencies will occur … in determining whether an actual controversy exists").

This is common sense. If speculative possibilities were enough to defeat declaratory jurisdiction, patent holders could never sue before the infringer actually launched its product, and, thus, inflicted the damage the patentee was attempting to avoid. Yet, courts routinely entertain such declaratory judgment actions before the damage occurs and before FDA approval. *See Novopharm,* 110 F.3d at 1571 (affirming jurisdiction about 16 months before FDA approval and marketing); *Kos Pharm.,* 242 F. Supp. 2d at 312, 318 (finding jurisdiction about a year or more before FDA approval based on a counterclaim to a March 2002 complaint where the earliest estimated approval date was March 2003); *Glaxo Group Ltd.,* 130 F. Supp. 2d at 1007-1008 (finding jurisdiction about 19 months before FDA approval where the complaint was filed in September 2000 and FDA approval was expected in June 2002).

Indeed, filing an application seeking FDA approval is exactly the sort of "concrete steps taken with the intent to conduct [infringing] activity" that the courts find sufficient to provide declaratory judgment jurisdiction. *See, e.g., Novopharm,* 110 F.3d at 1571 (affirming jurisdiction based on filing of FDA application); *Takeda Chem. Indus., Ltd. v. Watson Pharm., Inc.,* 329 F. Supp. 2d 394, 402 (S.D.N.Y. 2004) (upholding

jurisdiction based on application filing alone because "applying for FDA approval, show[s] that [party] has taken significant steps towards manufacturing and testing its … products"); *Astra Aktiebolag v. Andrx Pharms., Inc.*, 222 F. Supp. 2d 423, 425 (S.D.N.Y. 2002) ("[T]here is no question that all Defendants seek or have obtained FDA approval to sell the proposed ANDA product within the near future; therefore, the actual controversy requirement is met and the declaratory judgment action will be entertained"); *Glaxo, Inc. v. Torpharm, Inc.*, No. 95 C 4686, 1997 WL 282742, at *3 (N.D. Ill. May 18, 1997) ("[S]ince there is no question that TorPharm seeks imminent FDA approval to sell a [drug] in the near future, the actual controversy requirement is met and Glaxo's declaratory judgment action will be entertained").

In support of its argument that FDA approval is required to support jurisdiction, DexCom relies heavily on cases decided before the Federal Circuit's decision in *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997), where the Court made clear that FDA approval was *not* necessary for jurisdiction, and, upheld jurisdiction even though FDA approval was over a year away. DexCom's contention that *Glaxo* and the other cases that Abbott cites are distinguishable because they are pharmaceutical cases is misplaced. Contrary to DexCom's position, no court has ever held that there is a special rule for medical device cases – in contrast to pharmaceutical cases – requiring FDA approval for jurisdiction. Instead, DexCom's cases simply hold that it was too early in the application process for the court to entertain jurisdiction. For instance, in *Telectronics Pacing Systems v. Ventritex*, 982 F.2d 1520, 1527 (Fed. Cir. 1992), the Federal Circuit noted that the product "was *years away* from approval" and that the applicant "had only recently begun clinical trials" (emphasis added).

*Telectronics* certainly does not, as DexCom claims, stand for the proposition that FDA approval is required for declaratory jurisdiction.

To counter Abbott's contention that there is no special rule for medical device cases, DexCom cites a case that was decided after briefing had closed on DexCom's original motion to dismiss. (DexCom Opening Br. at 9 (citing *Benitec Austl. Ltd. v. Nucleonics, Inc.*, No. 04-0174 JJF, 2005 U.S. Dist. LEXIS 22008 (D. Del. September 29, 2005)). DexCom incorrectly implies that this case stands for the proposition that FDA approval is necessary for jurisdiction in a medical device case. Although the court in *Benitec* decided to decline jurisdiction, it specifically stated that its decision was based on the fact that "at the time the lawsuit was filed, [defendant] was several years away from obtaining FDA approval." *Benitec*, 2005 U.S. District. LEXIS 22008, at *9. The court further noted that the product was still "in clinical trials." *Id.* This is very different from the present case, where DexCom was only seven months away from approval and had completed all major regulatory hurdles to obtain approval at the time Abbott filed its initial Complaint.

DexCom also tries to distinguish the cases holding that subject matter jurisdiction may exist prior to FDA approval based on the mistaken classification of these cases as ANDA cases, subject to paragraph IV certifications. (DexCom's 1st Br. at 9). This distinction is misplaced. If these were ANDA cases, subject to paragraph IV certifications, declaratory judgment would not be necessary. 35 U.S.C. § 271(e). Instead, the filing of the ANDA itself is an act of infringement. *Id.*

**B. DexCom's Approval Was Not Only A Practical Likelihood, It Was A Foregone Conclusion.**

Unlike in *Telectronics* and *Benitec*, DexCom had not just begun clinical trials and was not "years away" from FDA approval when Abbott filed its initial Complaint. To the contrary, DexCom had successfully completed each and every step of the application process, including clinical trials, commercial inspections, and the pivotal 100-day meeting with the FDA. (D.I. 18 (Declaration of Timothy Goodnow at ¶ 5)). As explained in the affidavit of Timothy Goodnow, Abbott's Vice President of Research & Development, filed with Abbott's first Answering Brief, after DexCom completed those steps, the FDA could have approved DexCom's application at any time. (*Id.*). And it did, earlier than even Abbott expected, in March 2006.

Based on references in the public record, Abbott was able to demonstrate in its Complaint and original answering brief that FDA approval of DexCom's product was not only a practical likelihood, but a foregone conclusion. Abbott's assertion proved to be correct. The FDA granted "expedited" review of DexCom's product, (DexCom Press Release May 12, 2005; attached hereto as Ex. E), which means that DexCom's application was "placed at the beginning of the appropriate review queue and receive[d] additional review resources, as needed." (Expedited Review Guidance from FDA at Section C at 4; attached hereto as Ex. F). DexCom had completed its 100-day meeting with the FDA, during which the FDA was supposed to "inform [DexCom] of any identified deficiencies and what information is required to correct those deficiencies…." (100-Day Meeting Guidance from FDA at 1; attached hereto as Ex. G). According to DexCom, the FDA did *not* identify any substantial deficiencies at that meeting. Instead, the FDA asked certain questions that DexCom "consider[ed] … *readily answerable.*"

(DexCom July 25, 2005 Press Release (emphasis added); attached hereto as Ex. H). DexCom answered those questions in early September 2005. (September 12, 2005 Press Release; attached hereto as Ex. I).

DexCom also had completed its clinical trials, despite insisting that it had not. In fact, even before Abbott filed its Complaint, DexCom announced that the FDA "did *not* make any request for DexCom to conduct additional clinical studies" at the 100-day meeting. (Exhibit H (emphasis added)). And DexCom repeatedly stated that such clinical trials would *not* be necessary because it *already* "met [its] primary safety and efficacy end points" through its earlier clinical trials. (Tr. of CEO Speech, June 23, 2005; attached hereto as Ex. J).

DexCom also successfully passed its commercial inspections. On August 2, 2005, DexCom "announced the successful completion of two key inspections related to the FDA review of the PMA application." (DexCom August 2, 2005 Press Release; attached hereto as Ex. K). DexCom stated that "[s]uccessfully completing BIMO and QSR inspections is a very significant achievement for DexCom as we progress toward being a commercial enterprise capable of launching a product, *especially as the inspections occurred earlier than we would have expected, only four months after filing our first-ever PMA.*" *Id.* (emphasis added).

In short, DexCom had cleared every regulatory step necessary for approval when Abbott filed its Complaint. This proved true when DexCom received Approval in March 2006, ahead of schedule. Accordingly, it was clear that approval and launch of an infringing device was imminent, despite DexCom's repeated protestations

that it was not. There is no doubt that declaratory jurisdiction existed at the time Abbott filed its initial Complaint, and jurisdiction continues to exist today.

## III. DexCom's Rule 12(b)(6) Motion To Dismiss Abbott's Patent Infringement Allegations in Connection with Trade Shows Should Be Denied; DexCom Actually Infringed Abbott's Patents Before Abbott Filed Its Complaint.

This Court had subject matter jurisdiction over this case under the patent laws when Abbott filed its initial Complaint because DexCom actually infringed Abbott's patents by showcasing its product at trade shows. DexCom has continued to infringe Abbott's patents since that time.

### A. Abbott's Allegations Met the Rule 12(b)(6) Standard.

DexCom erroneously argues that there was no jurisdiction over Abbott's initial Complaint because Abbott failed to state a claim pursuant to Rule 12(b)(6). Putting aside that Rule 12(b)(6) has nothing to do with jurisdiction, because of DexCom's approval and launch there has been sufficient infringement since the launch to moot DexCom's argument. Nevertheless, even without the post-filing infringement, Abbott met its burden of alleging sufficient facts to withstand a challenge based on Rule 12(b)(6).

Dismissal under Rule 12(b)(6) is appropriate only when "'it is clear that no relief can be granted under any set of facts that could be proved consistent with the allegations.'" *H.J. Inc. v. Northwestern Bell Tel. Co.*, 492 U.S. 229, 249-50 (1989) (quoting *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)). In fact, it must be "beyond doubt" that the "pleader can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). When making that assessment, district courts must "construe[] the facts in favor" of the plaintiff. *Stiner v. Univ. of Delaware*, 243 F. Supp. 2d 106, 116 (D. Del. 2003).

DexCom did not dispute that Abbott properly alleged infringement, which in itself moots DexCom's Rule 12(b)(6) arguments. Instead, DexCom argues that everything it did fell within the exception afforded by § 271(e). DexCom's assertions ignore the standards of § 271(e) and recent case law from the Supreme Court interpreting that section.

First, Abbott plainly alleged in its original Complaint that DexCom's activities were not covered by § 271(e)(1). Section 271(e)(1) applies, on its face, only when the infringing activity is "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1). Moreover, the Supreme Court has held that § 271(e)(1) presents a factual issue about whether there is a "reasonable basis for believing that [disputed] experiments will produce the types of information that are relevant to an IND or NDA" filing with the FDA. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2383 (2005). DexCom ignores this case, which Abbott cited in its original answering brief.

Abbott's Complaint plainly alleged facts taking DexCom outside the protection of § 271(e)(1) under the *Merck* standard. Abbott alleged that DexCom made infringing products "for the purpose of showcasing [them] at the trade shows rather than for the purpose of gathering information for submission to the FDA," and, similarly, that "DexCom's manufacture of its product for the purpose of showcasing it at trade shows constitutes an infringing act, not exempted by 35 U.S.C. §271(e)(1) relating to the collection of information for submission to the FDA." (Complaint at ¶¶ 16 , 17, and 28).

That ends the analysis, because Abbott's allegations must be accepted as true under Rule 12(b)(6). DexCom nevertheless asks this Court to disregard Abbott's allegations. Specifically, DexCom asserts that the FDA "may require" additional clinical trials for DexCom's STS system and that it really made the commercially-slick samples to seek clinical investigators at trade shows to "prepar[e] for possible additional clinical trials." (DexCom's 1st Br. at 14-16). To support these assertions, DexCom filed a declaration from one of its own employees (D.I. 8) and more than 400 pages of exhibits (D.I. 7).

DexCom also ignores the case Abbott cited in its original answering brief from the Southern District of Florida, which rejected a nearly identical argument by an accused infringer. In the context of a motion to dismiss under Rule 12(b)(6), the infringer – just like DexCom – made arguments and filed an employee's affidavit claiming that its activities were protected by § 271(e)(1). *Ventrassist Pty Ltd. v. Heartware, Inc.*, 377 F. Supp. 2d 1278, 1288 (S.D. Fla. 2005) *adopted by* 377 F. Supp. 2d 1278, 2005 U.S. Dist. LEXIS 18457 (S.D. Fla. 2005). The district court found, not surprisingly, that an accused infringer cannot obtain dismissal by contradicting a complaint's allegations. *Id.* In fact, the district court found that § 271(e)(1) is *never* the proper subject of a motion to dismiss under Rule 12(b)(6) because § 271(e)(1) is an affirmative defense and "Plaintiffs are not required to negate an affirmative defense in their complaint." *Id.* at 1281.

For the very same reasons, this Court should reject DexCom's motion to dismiss. There is no question that Abbott's initial Complaint stated a claim for patent

infringement, and specifically alleged that DexCom's activities were not for the purpose of gathering information for the FDA.

**B. DexCom's Summary Judgment Cases Under Rule 56 Provide No Basis For A Motion To Dismiss Under Rule 12(b)(6).**

In an effort to obtain dismissal despite Abbott's clear allegations, DexCom relies solely on pre-*Merck* summary judgment cases and does not even consider Abbott's cases cited in its original Answering Brief. In each case that DexCom cites, the issue was resolved on summary judgment under Rule 56, not on the pleadings under Rule 12(b)(6). *Telectronics*, 982 F.2d at 1521 (reviewing an "order granting the defendant's motion for summary judgment"); *AbTox Inc. v. Exitron Corp.*, 122 F.3d 1019, 1020 (Fed. Cir. 1997) (reviewing "cross motions for summary judgment"); *Nexell Therapeutics, Inc. v. Amcell Corp.*, 199 F. Supp. 2d 197, 198-199 (D. Del. 2002) ("AmCell moved for summary judgment of non-infringement" based on 35 U.S.C. § 271(e)(1)); *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1270 (N.D. Cal. 1991) (considering cross motions for summary judgment).

DexCom also completely ignores *Merck*, where the Supreme Court held that analysis under § 271(e)(1) turns on whether there is a "reasonable basis" for concluding that the disputed activity would "produce the types of information" filed with the FDA. 125 S. Ct. at 2383. Far from suggesting this was a legal issue susceptible to resolution on the pleadings under Rule 12(b)(6), the Supreme Court declined to review "the sufficiency of the evidence" supporting a *jury's verdict*, and, thus, remanded the case for further proceedings before the Federal Circuit. *Id.*

DexCom's own pre-*Merck* cases are consistent. In *Teletronics*, for instance, the Federal Circuit affirmed summary judgment only because the "basic facts

[were] undisputed." *Telectronics Pacing Sys. v. Ventritex, Inc.*, 982 F.2d 1520, 1521 (Fed. Cir. 1992). The court explained that the accused infringer presented evidence showing that its medical conference "demonstrations ha[d] all been set up for the purpose of obtaining clinical investigators," which the court found supported summary judgment "[a]bsent some showing that [the infringer's proffered] purpose is disputed." *Id.* at 1523. It further noted that the "fact that some non-physicians may have seen the device at the conferences is merely incidental and of minimal import, since only physicians can implant the device." *Id.*

Here, of course, Abbott does dispute the notion that DexCom, a small company with limited resources, spent considerable resources setting up glitzy product displays simply to solicit clinical investigators – a claim that is all the more suspect because DexCom argues that it was seeking investigators for unspecified "possible" clinical trials that, in fact, the FDA had previously indicated would not be necessary. (Ex. H). Moreover, unlike in *Telectronics*, DexCom's product is implanted by non-physician patients who attended both conferences in droves, making it all the more clear that DexCom was simply generating buzz in anticipation of a product launch. Given these facts, Abbott quite specifically alleged that DexCom made product samples simply "for the purpose of showcasing [them] at the trade shows rather than for the purpose of gathering information for submission to the FDA." (Complaint at ¶¶ 16 , 17, and 28).

It is simply not reasonable, given Abbott's allegations, for DexCom to seek a pre-discovery dismissal under Rule 12(b)(6), which requires that Abbott's allegations be accepted as true and accurate. DexCom's own affidavit leaves open many factual questions that will be resolved through discovery, most particularly whether

DexCom actually solicited any clinical investigators at the conference. In the end, there is no basis for granting DexCom's motion to dismiss. Abbott has specifically alleged facts demonstrating that DexCom's activities infringed Abbott's patents and were not protected by § 271(e)(1). Nothing more is required at the notice pleadings stage.[2]

## IV. From a Judicial Economy Standpoint, It Makes Sense to Deny DexCom's Motion.

Because the Court clearly has discretion to allow amendments, Abbott's Amended Complaint should be allowed from a judicial economy standpoint. There is no dispute that if Abbott filed its Amended Complaint as a new action, there would be no question about the Court's jurisdiction, and DexCom would have no basis to file a motion to strike or dismiss. Accordingly, in the interests of judicial economy, it simply makes sense to continue the present dispute between the parties, who have already conducted discovery and begun the claim construction process, rather than requiring Abbott to start over with a new complaint.

## V. DexCom's Latest Motion is Nothing More Than Another Tactical Maneuver.

Rather than dealing head-on with Abbott's infringement allegations, DexCom has instead embarked on a scorched earth litigation strategy, with the apparent

[2] Abbott also objects to DexCom's request in its initial Motion to Dismiss for the Court to take judicial notice of its various press releases and SEC filings, and, in doing so, to also accept the truth of statements made in those documents. That is not a proper use of judicial notice. DexCom is seeking judicial notice of easily-disputed facts regarding its purpose for making the product samples in question as well as the prospect and likelihood of clinical trials. But Federal Rule of Evidence 201 only applies to facts "not subject to reasonable dispute." Fed. R. Evid. 201; *Oran v. Stafford*, 226 F.3d 275, 289 (3d Cir. 2000) (judicial notice of properly-authenticated public disclosure documents filed with SEC is appropriate for proving documents' content, not truth of their content) (citing *Kramer v. Time Warner, Inc.*, 937 F.2d 767, 774 (2d Cir. 1991)).

goal of pushing the inevitable infringement finding as far into the future as possible. To that end, DexCom filed its first motion to dismiss on exactly the same subject matter jurisdiction grounds as the present motion, refused to even discuss a discovery schedule with Abbott, and then dragged its feet through the discovery process. DexCom also submitted reexamination requests on 163 claims in four of Abbott's patents, which largely amounted to nothing more than run-of-the-mill obviousness arguments based on references that were already considered by the PTO. DexCom also filed a motion to stay this case pending reexamination, despite the flimsy nature of its reexamination arguments and the fact that it is highly improbable that the PTO will invalidate all the claims DexCom infringes.

DexCom's strategy to avoid judicial resolution of Abbott's infringement contentions is crystal clear and should not be rewarded. The fact that there are seven patents at issue is not a basis to allow DexCom to continue to reap the profits it is realizing from copying Abbott's technology and piggybacking on Abbott's enormous investment in the development of this technology. Rather, the fact that there are seven patents at issue simply shows that DexCom contributed absolutely nothing to the development of this technology.

Abbott properly filed its patent infringement case based on four patents after DexCom showcased its infringing product at trade shows and was far along in the FDA approval process. Abbott properly amended its Complaint to assert three additional patents before DexCom answered the initial Complaint, within the time for amending pleadings set by the Court, and about a month after DexCom produced its first meaningful discovery responses.

DexCom's latest motion is nothing more than an attempted roadblock to prevent Abbott from enforcing its patents. If courts applied the arguments advanced by DexCom in this case, it would be nearly impossible for a patentee to prevent an infringer from launching an infringing product, infringers could derail litigation simply by taking advantage of the low threshold for the granting of reexamination requests, and a patentee could never amend as of right under Rule 15(a) if the infringer engaged in further acts of infringement after the filing of the initial complaint. DexCom's arguments are contrary to the patent laws and the Federal Rules of Civil Procedure. DexCom's motion to strike or dismiss Abbott's Amended Complaint should be denied.

## CONCLUSION

For the foregoing reasons, Abbott respectfully requests that this Court deny DexCom's Motion To Strike and Renewed Motion to Dismiss.

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**CERTIFICATE OF SERVICE**

I hereby certify that on July 27, 2006, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

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Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on July 27, 2006 upon the following individuals in the manner indicated:

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